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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,008	01/03/2006	Sanjay Suri	05-40052-US	8800
<div>7590 06/27/2007</div> <div>Louis M Heidelberg Reed Smith 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103</div> <div>EXAMINER DESAI, RITA J</div> <div>ART UNIT PAPER NUMBER 1625</div> <div>MAIL DATE DELIVERY MODE 06/27/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,008	Applicant(s) SURI ET AL.	
	Examiner Rita J. Desai	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/06;10/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-15 are pending.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is independent, without any limitation of what the process is for.

The examiner is assuming that the process is dependant on claim 1.

Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the following references independently.

- 1) WO -A -9510514, 1995, Bhisop Robert et al
- 2) Chemical and Pharmaceutical Bulletin, JP (11-1999), 42(11) 2285-2290. Iwasaki et al
- 3) Tetrahedron 1998... Sejas et al
- 4) WO -A- 9631478, 1996, Afonso et al.

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- 5) EP 0,208, 855 cited in application page 3.
- 6) EP 0,152,897 cited in application page 3.
- 7) US, 4,659,716 cited in application page 3.
- 8) Hu 194,864 cited in application page 2.

Applicants claims are drawn to a process of making DCL (Desloratadine) from Loratadine by reacting it with neat alcohol in the presence of a base.

Scope and Content of the Prior Art

All the above prior art disclose the process of making DCL in the presence of aqueous alcohol and a base.

- 1) WO -A-9510514, 1995, Bishop Robert et al at page 52.
- 2) Chemical and Pharmaceutical Bulletin, JP (11-1999), 42(11) 2285-2290. Iwasaki et al , see page 8829 experimental section preparation of compound 4a.
- 3) Tetrahedron 1998... Sejas et al see page 6200, example 3H.
- 4) WO -A- 9631478 , 1996, Afonso et al. see page 26, line 10-15.
- 5) EP 0,208, 855 cited in application page 3.
- 6) EP 0,152,897 cited in application page 3.
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Difference between the prior Art and Applicants invention

The difference is in the fact that applicants use Neat alcohol instead of the aqueous alcohol .

Prima facie Case of Obviousness

DCL and Loratadine are very well known commercial compounds.

There are several process of making DCL from Loratadine using alcohol and a base. The difference is in using a neat alcohol.

The motivation of making a different process comes from the fact that DCL is a very commercial and profitable compounds used in pharmaceuticals.

To a chemist who is in the field of synthesis and purification, it is within the scope of routine experimentation to change solvents, temp, well known isolation techniques such as filtration and such to come up with a process that would have a improvement over an old process.

Applicants in their specification do not have a side by side comparison to show what and to what extent the improvement is .

It is known that neat alcohol would be more reactive and efficient than an aqueous solvent.

Neat alcohol is routinely used in fuel cells. The proton transfer is form a neat alcohol is known to be faster.

Thus it is prima facie obvious for a chemist to modify the process of the prior art to see if they can obtain a process which gives better yield, or less waste, or less impurities, or just faster.

Applicants specification fails to show what the improvement is. There are several cited references in the specifications on pages 2 and 3, and applicants clearly state that they teach the process in which aqueous alcohol is used with an inorganic base.

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Applicants modification of using the neat alcohol instead of aqueous alcohol is not patentably distinct.

All the above rejections also in view of Peon Jorge et al , 2001 Solvent reorganization Controls the rate of proton transfer ...

Jorge et al , 2001 teaches that the proton transfer in neat solvents especially in methanol is fastest . See abstract.

In view of this teaching and also the fact that fuel cells customarily use neat solvents , the motivation to use it in a process to make it more efficient is clearly taught and to a chemist it would be within the scope of routine experimentation to try a neat solvent , as changing solvents and experimental conditions is something a chemist routinely tries to modify a process.

Conclusion

Claims 1-15 are rejected.

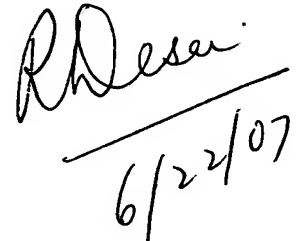
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andrés can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625



6/22/07

R.D.
June 22, 2007